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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/277,091	03/19/99	GRASSO	19705-001-(A

VB

12/12/12

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EXAMINER	
SAOUD, C	
ART UNIT	**PAPER NUMBER**
1647	7

DATE MAILED: 12/19/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/377,081	Applicant(s) GRASSO et al.
	Examiner Christine Saoud	Group Art Unit 1647

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-42* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-42* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-18, and 39 drawn to a leptin peptide and compositions thereof, classified in class 514, subclass 2, for example.

II. Claims 19 and 21-25, drawn to a method of treating a pathophysiology, classified in class 514, subclass 2, for example.

III. Claims 20-25, drawn to a method of preventing a pathophysiology, classified in class 514, subclass 2, for example.

IV. Claims 26-30, 35 and 39, drawn to nucleic acids, vectors, host cells and recombinant methods of production of a leptin peptide, classified in class 435, subclass 69.1, for example.

V. Claims 36-39, drawn to antibodies, classified in class 530, subclass 387.1, for example.

VI. Claim 40, drawn to a transgenic animal, classified in class 800, subclass 2.

VII. Claim 41, drawn to a method of identifying a drug, classified in class 514, subclass 2, for example.

VIII. Claim 42, drawn to a method of identifying a modulator, classified in class 435, subclass 4, for example.

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and (II-III and VII-VIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the peptides of Group I could be used in an entirely different method, such as in a method of generating antibodies rather than in either of the methods of Groups II, III, VII or VIII.

Inventions I and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case the polypeptide of Group I could be made by an entirely different method (such as synthetically) rather than by the method of Group IV.

4. Inventions I and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the peptides of Group I could be used to make the antibodies of Group V, but the peptides could also be used in methods of treatment or prevention, as in Groups II-III. Furthermore, the peptides of Group I and the antibodies of Group V are structurally and functionally distinct compounds which are unrelated because they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

5. Inventions I and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to different products in that the peptides of Group I are not required for the transgenic animal of Group VI, and the transgenic animal is not required for the peptides of Group I.

6. Inventions II, III, VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to distinct methods which have different goals, starting materials and/or method steps, and are therefore, not related.

7. Inventions II and (IV-VI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to a method of treating (Group II) and to several different products (Groups IV-VI), wherein the inventions are not disclosed as capable of use together in that the method of Group II does not require any of the products of Groups IV-VI .

8. Inventions III and (IV-VI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the

different inventions are directed to a method of prevention (Group III) and to several different products (Groups IV-VI), wherein the inventions are not disclosed as capable of use together in that the method of Group III does not require any of the products of Groups IV-VI .

9. Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to distinct products which are not disclosed as capable of use together in that the nucleic acids and the antibodies are physically and functionally distinct, have different modes of operation, different functions and different effects.

10. Inventions IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the DNA of Group IV could be used in a method of protein production rather than in a method of making a transgenic animal of Group VI.

11. Inventions IV and (VII-VIII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to a product (Group IV) and to several different methods

(Groups VII-VIII), wherein the inventions are not disclosed as capable of use together in that the methods of Groups VII-VIII do not require the product of Group IV.

12. Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to distinct products which are not disclosed as capable of use together, have different modes of operation, different functions, and different effects.

13. Inventions V and VII-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to a product (Group V) and to several different methods (Groups VII-VIII), wherein the inventions are not disclosed as capable of use together in that the methods of Groups VII-VIII do not require the product of Group V.

14. Inventions VI and VII-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to a product (Group VI) and to several different methods (Groups VII-VIII), wherein the inventions are not disclosed as capable of use together in that the methods of Groups VII-VIII do not require the product of Group VI.

15. The inventions of each named pair can be shown to be distinct because they do not rely upon each other for their ultimate use and they require non-coextensive literature searches. The compounds are physically and functionally distinct and are not required one for the other and the methods have different goals, method steps, and/or starting materials.

16. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the necessity for non-coextensive literature searches, restriction for examination purposes as indicated is proper.

Species Election

17. This application contains claims directed to the following patentably distinct species of the claimed invention: peptides having 70% homology to any one of amino acid sequences SEQ ID NO:2-16 and 18, peptides having the amino acid sequence of Claim 4, or peptides having any one of the sequences of Claim 12.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is entirely generic. Applicant is advised that the election must be a single, molecular embodiment of peptide to be examined (i.e. having a specific amino acid sequence) in order to be responsive to this requirement.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon,

including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

18. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud, Ph.D., whose telephone number is (703) 305-7519. The examiner can normally be reached on Monday to Friday from 7AM to 3PM. If attempts to reach

the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556. If this number is out of service, please call the Group receptionist for an alternate number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

December 18, 2000

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine J. Saoud